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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,549	02/28/2002	Brigitte Chau Phan	BT12 00102703(USP3) USP8	3006
20995	7590	06/20/2006	EXAMINER FORMAN, BETTY J	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/087,549	Applicant(s) PHAN ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8, 10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 April 2006 has been entered.

Status of the Claims

2. This action is in response to papers filed 18 April 2006 in which claims 1, 7, 9 and 11 were amended. the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 18 October 2005, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1, 7, 9 and 11 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

Art Unit: 1634

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al (WO 00/26677, published 11 May 2000) in view of Collins et al (U.S. Patent No. 5,750,338, issued 12 May 1998).

Regarding Claim 1, 7, 9 and 11, Worthington et al discloses a method for identifying presence of a target. The method comprises the steps of preparing a test sample having target DNA, preparing reporters having signal DNA which is complementary to the target, preparing capture DNA complementary to the target DNA and immobilized on magnetic capture beads (Fig. 36, page 49, lines 21-35 and page 89, lines 17-28) and having an anchor agent (e.g. aminated terminus for biotin anchor, page 88, lines 26-28), blocking the beads with a blocking agent (e.g. PBSAz, page 80, lines 29-32), depositing the beads and test sample into a mixing chamber of an optical bio-disc, rotating the bio-disc allowing the beads to move into the target zone having an anchor agent for the capture agent removing non-complexed beads and detecting bead complexes to determine presence of the target DNA (Example 7, pages 88-92). Worthington et al further teach target nucleic acids (page 50, lines 4-16).

The instant claims differ from the teaching of Worthington et al in that while the reference teaches sandwich assay (Fig. 36) wherein two moieties (one a magnetic bead and one biotin-PEG, page 88, lines 28-34) each having target specific sequences, the reference does not specifically teach both moieties are pre-treated beads and detection of a dual bead complex wherein the target is RNA. However, the reference (Fig. 39) clearly illustrates detection of multiple single-bead complexes at high magnification. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the sandwich hybridization of Worthington et al attaching a bead to both the probes to thereby provide a larger and more visible target-probe complex. One of ordinary skill in the art would have been motivated to do so to thereby optimize detection of the target.

Art Unit: 1634

Furthermore, pre-treatment of magnetic beads and bead-RNA target complexes and their detection was well known in the art at the time the claimed invention was made as taught by Collins et al who specifically teach pretreatment of beads to block non-specific binding sites (Column 21, lines 18-21).

4. Claims 1, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oprandy (U.S. Patent No. 5,679,519, issued 21 October 1997) in view of Collins et al (U.S. Patent No. 5,750,338, issued 12 May 1998) and Virtanen (WO 98/38510, published 3 September 1998).

Regarding Claim 1, 7, 9 and 11, Oprandy teaches a method for identifying presence of a target. The method comprises the steps of preparing a test sample having target DNA or RNA (Column 5, lines 49-51), preparing reporter beads (ECL particle, Column 6, lines 34-67) having signal DNA which is complementary to the target (Column 7, lines 4-28), preparing capture DNA complementary to the target DNA and attached to magnetic beads (Column 7, lines 28-49) and having an anchor agent (e.g. biotin anchor, Column 7, lines 40-49), depositing the beads and test sample into a mixing chamber, allowing the beads to move into the target zone having an anchor agent for the capture agent removing non-complexed beads (electrode capture of the magnetic particles and washing to remove unbound and detecting bead complexes to determine presence of the target DNA (Column 3, line 54-Column 4 and line 25; Examples 1-6). The instant claims differ from the teaching of Oprandy in that the reference teaches complex detection on an electrode, the reference is silent regarding pretreatment of the beads and optical bio-disc detection.

However, pre-treatment of beads was well known in the art at the time the claimed invention was made as taught by Collins et al who specifically teach pretreatment of beads

Art Unit: 1634

blocks non-specific binding sites (Column 21, lines 18-21) and application of a magnetic field to isolate the target-bead complex (Column 22, lines 5-48). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the bead pre-treatment of Collins et al to the method of Oprandy for the expected benefit of blocking non-specific binding sites as desired in the art (Collins, Column 21, lines 18-21).

Furthermore, Virtanen teaches that an optical bio-disc "combines diagnostic assays with computers and compact disk technology. In its most preferred embodiment, a computer with a compact disk reader is the only instrument needed. All chemistry is performed inside a compact disk that may be referred to as an integrated biocompact disk (IBCD). The same compact disk is also encoded with software, i.e., machine-readable instructional and control information, that provides instructions to a computer prior to, during and after the assay." (page 2, lines 6-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the bio-disc of Virtanen in the method of target-bead complex detection for the expected benefit of quick, efficient, accurate and low-cost diagnostics as taught by Virtanen (page 2, lines 4-12).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1634

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 7, 9 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/997,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for identify the presence of a target and differ only in that the instant claims are drawn to the genus method wherein the beads are generic, the isolation/capture method step is generic, the sample is generic and the target is generic. In contrast, the '711 claims define bead species (e.g. magnetic), isolation species (e.g. magnetic capture), sample species (e.g. blood, plasma, etc.) and target species (e.g. nucleic acid, protein, etc.).

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed genus is obvious in view of the '711 species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Comments

7. Applicant states that a terminal disclaimer will be filed, if necessary, upon resolution of claim rejections. Applicant's statement is noted. The rejection is maintained.

8. Claims 1, 7, 9 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending

Art Unit: 1634

Application No. 10/099,266. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for identify the presence of a target using a dual bead assay and differ only in the that the '266 claims are further drawn to digestion of the dual bead complex. However, the instant claim language "comprising" encompasses the additional limitations of the '266 claims. Therefore, the claim sets are not patentably distinct.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

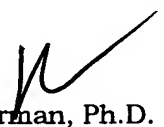
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables

Art Unit: 1634

applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 14, 2006